

REMARKS

Claims 3-12 and 14-17 are pending in this application. Claims 3-12 and 14-17 are rejected. In view of the following remarks, reconsideration of claims 3-12 and 14-17 is respectfully requested.

Claim Rejections - 35 USC § 103

Claims 3-12 and 14-17 have been rejected under 35 U.S.C. 103(a) as being obvious over Hiserodt *et al.* (US patent No. 6,277,368) and in view of Armistead *et al.* (US patent No. 5,717,092).

Hiserodt *et al.* is directed to the use of a vaccine in cancer immunotherapy. As mentioned in the abstract of Hiserodt *et al.*, the disclosed vaccines only comprise a source of tumor-associated antigen and a cytokine-secreting cell-line. Although Hiserodt *et al.* recites that the Hiserodt compositions may be given following, preceding, in lieu of, or in combination with, other cancers therapies (e.g. radiation therapy, chemotherapy) (See ¶ 140 of Hiserodt *et al.*), the only time Hiserodt *et al.* uses a combination therapy that involves administering a chemotherapeutic agent and a vaccine containing tumor cells to cancer patients is in Example 7 where the chemotherapeutic agent Cisplatin is administered to ovarian cancer patients nine days after these patients received the last injection of the Hiserodt vaccine. Thus, as acknowledged by the Examiner (See ¶7 of the Final Office Action), Hiserodt *et al.* does not teach a single composition that contains tumor cells, chemotherapeutic agent, and carrier, as recited in claim 3 of the instant application. Moreover, Hiserodt *et al.* cautions that radiation therapy and adjuvant chemotherapy be used "in a way or at a time that does not interfere with the immunogenicity of the Hiserodt compositions ". (See ¶ 140 of Hiserodt *et al.*). Thus, Hiserodt *et al.* suggests that there is considerable unpredictability in the art of anti-cancer immunogenic compositions. In other words, one of ordinary skill in the art, upon reading Hiserodt *et al.* as a whole, would **not** reasonably believe that the immunogenic composition recited in claim 3 of the instant application would be efficacious, much less that adding a chemotherapeutic agent to a composition containing inactivated tumor cells would greatly enhance the immunogenicity of such a composition as shown in Examples III and IV of the instant application

Armistead *et al.* does not provide the teachings and suggestions absent from Hiserodt *et al.* Armistead *et al.* is not directed at enhancing the immunogenicity in a patient of compositions that contain inactivated tumor cells. Instead, as mentioned in column 18, lines 62-64, Armistead *et al.* is directed to methods for treating or preventing multi-drug resistance in cancer cells. Moreover, unlike the compositions of the instant claims, which comprise inactivated tumor cells and chemotherapeutic agents, the compositions of Armistead *et al.* contain two related classes of compounds. (See first sentence in the Detailed Description of the Invention in Armistead *et al.*) Thus, the teachings in Armistead *et al.* do not apply to the vaccines of Hiserodt *et al.* Accordingly, upon reading both Hiserodt *et al.* and Armistead *et al.*, the skilled artisan still would not reasonably expect that that the immunogenic composition recited in claim 3 of the instant application would be efficacious, much less that adding a chemotherapeutic agent to a composition containing tumor cells would greatly enhance the immunogenicity of such a composition. Accordingly, applicants submit that claim 3, and the claims that depend therefrom, i.e., claims 4-12 and 14-17, are not obvious over Hiserodt *et al.* in view of Armistead *et al.*

Claims 3-12 and 14-17 are rejected under 35 U.S.C. 103(a), as being obvious over Wang *et al.* (Cancer Immunol., 1986) and in view of Armistead *et al.* (US patent No. 5,717,092).

Wang *et al.* recites the administration of CL 259,763 to animals by gavage (see page 8, second column, fourth paragraph of Wang *et al.*). Further, it is clearly indicated in Wang *et al.* (page 10, first column, third paragraph) that the mice were vaccinated with L1210 tumor cell and subsequently given this test compound by gavage. Thus, the combination therapy of Wang *et al.* is similar to the combination therapy of Hiserodt *et al.* except that the test compound of Wang *et al.* was given in a **different way** as well as at a **different time** as the tumor cells. Accordingly, given the unpredictability in the anti-cancer immunogenic composition art, Wang *et al.* is even less likely to motivate one of ordinary skill in the art to add a chemotherapeutic compound to a composition that comprises tumor cells. Furthermore, as indicated above, the compositions recited in Armistead *et al.* do not contain inactivated tumor cells, and the problem being addressed by Armistead *et al.* is different from the problem being addressed by Wang *et al.* Accordingly, upon reading both Wang *et al.* and Armistead *et al.*, the skilled artisan still would not reasonably expect that that the immunogenic composition recited in claim 3 of the instant application would be efficacious, much less that adding a chemotherapeutic agent to a

composition containing tumor cells would greatly enhance the immunogenicity of such a composition. Accordingly, applicants submit that claim 3, and the claims that depend therefrom, i.e., claims 4-12 and 14-17, are not obvious over Wang *et al.* in view of Armistead *et al.*

It is submitted therefore that the claims are in condition for allowance. Allowance of claims 3-12 and 14-17 at an early date is respectfully solicited.

In the event that there are any questions concerning this response, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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